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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,902	CHERR ET AL.	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 37-55* is/are pending in the application.

4a) Of the above claim(s) *1-34,38,45-48 and 53-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,37,39-44 and 49-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on January 20, 2004 wherein claim 35 has been amended and claim 36 is cancelled.

Currently, claims 1-35 and 37-55 are pending in this application.

As recorded in the previous Office Action July 1, 2003, Claims 1-34, 38, 45-48, and 53-55 and are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 35, 37, 39-44 and 49-52 are examined on the merits herein.

Applicant's amendment which cancels claim 36 filed on January 20, 2004 with respect to the objections of record stated in the Office Action dated July 1, 2003 has been fully considered and is found persuasive. Therefore, these objections are withdrawn.

Applicant's amendment adding the negative limitation "wherein the polyvinylsulfonic acid is other than a polystyrene sulfonate" herein in claim 35 and canceling claim 36 filed on January 20, 2004 with respect to the rejection of claims 35-36 made under 35 U.S.C. 102(b) as being anticipated by Anderson et al. of record in the previous Office Action July 1, 2003 has been considered and found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37, 39, 42, 43-44, 49, and 51 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular sulfonated compound in claim 37 (e.g., a lignosulfonic acid, also known as a lignosulfonate, ligninsulfonate, lignosulfate, or poly(lignosulfonic acid, see the other names of lignosulfonic acid provided by STN Registry, PTO-892), in combination with the only one particular spermicide, Nonoxynol 9^{TM} (see page 6 line 1 of the specification herein) with or without a sperm, in pharmaceutical compositions herein, does not reasonably provide enablement for any sulfonated compounds isolated from a natural source or any derivatives of a lignin in claims 49 and 51, and any compounds having spermicide function (i.e., in claims 39 and 43), for the same reasons of record in the previous Office Action July 1, 2003.

Response to Argument

Applicant's arguments filed January 20, 2004 with respect to this rejection made under 35 U.S.C. 112, first paragraph, for lack of **full** scope of enablement have been fully considered but are not deemed persuasive as further discussed below.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required

undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors as discussed in the previous Office Action.

Applicant assertions that "no matter which standard is applied, the specification presents ample guidance and direction for those of skill in the art to perform the invention", and "For example, in terms of determining sulfonated compounds of the invention, the specification presents guidance such as, e.g., Examples 1-3 and Figure 7, etc., which set out experimental details to help in delineation of possible compounds" have been considered but not found convincing. As noted in MPEP 2111, during patent examination, claims are given their **broadest** reasonable interpretation. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim, However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) for example. In this case, as discussed in the previous Office Action, the instant claims read on administering to a host (i.e., a mammal) any sulfonated compounds isolated from a natural source or any derivatives of a lignin in claims 49 and 51, and/or any compounds having spermicide function, which broadly encompass those known and unknown sulfonated compounds isolated from a natural source and spermicides, as of the instant filing date, as well as those future known sulfonated compounds isolated from a natural source and spermicides.

Moreover, as pointed out in the previous Office Action one skilled in the art would clearly recognize that any sulfonated compounds isolated from a natural source would

encompass numerous or may be a million different compounds having various structures and possessing very different functional properties or activities. Moreover, the recitation, spermicide, is seen to be merely functional language. One skilled in the art would understand that any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physiological effects and functions.

Further, as discussed in the previous Office Action, regarding "a derivative of a lignin", it is known that not any derivatives of lignin are bioactive or having pharmaceutical activities, but only those ligin-derived macromolecules (LDM) containing lignosulfonate or sulfonated (or sulfated) derivatives according to the teachings of Pillai et al. (see abstract and page 140-141, "34" in PTO-1449 submitted November 25, 2002). Cherr et al. also teaches that those low molecular weight polar compounds in the fraction in the isolation of LDM from liginin, are not bioactive (see the bottom of the right column at page 523, "17" in PTO-1449 submitted November 25, 2002). Thus, not all derivatives of lignin have enablement for the instant invention.

Furthermore, contrary to Applicant's assertion that "the specification presents guidance such as, e.g., Examples 1-3 and Figure 7, etc., which set out experimental details to help in delineation of possible compounds", notes that only a single particular sulfonated compound, LSA (a lignosulfonic acid) were tested in Examples 1-3 and Figure 7, and that the other sulfonated compound, polyanetholesulfonic acid (PASA) was tested in working examples in the specification (see page 21-30).

As indicated in the previous Office Action, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without

undue experimentation. As noted in MPEP 2164.01, "Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In the instant case, as discussed above, the claims herein especially broadly encompass those unkonown sulfonated compounds isolated from a natural source or those unkonown derivatives of a lignin, and/or unknown spermicides, as of the instant filing date, as well as those future known sulfonated compounds isolated from a natural source, derivatives of a lignin, and spermicides. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention, for example, requiring additional or future research to establish or verify any compounds whether having functions recited in the instant claims and their usefulness.

Thus, contrary to Applicant's assertion that "no undue experimentation is needed to do so", the specification fails to provide clear and convincing evidence in sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the

embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

As discussed in the previous Office Action, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host (e.g., a male or a female, or *vivio*) the ***combination*** of any compounds represented by any sulfonated compound isolated from a natural source or any derivative of a lignin, and any compound having spermicide function in a composition. See text book "Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding possible drug-drug interactions (9th ed, 1996) page 51 in particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed" and that "The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right column of page 51) (emphases added). Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent

protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test all compounds encompassed in the instant claims and their combinations employed in the claimed compositions to be administered to a host, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35, 37, 49 and 51-52 are rejected under 35 U.S.C. 112, second paragraph, for indefinite recitations, "derivatives thereof" in the end of claims 35 and 37 and "a derivative thereof" in the end of claim 49, for the same reasons of record in the previous Office Action July 1, 2003.

Applicant's remarks filed January 20, 2004 with respect to this rejection made under 35 U.S.C. 112, second paragraph in the previous Office Action have been fully considered but are not deemed persuasive as further discussed below.

As pointed out above, during patent examination, claims are given their **broadest** reasonable interpretation. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim, However, it is not proper to

read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) for example.

The recitations, "derivatives thereof" and "a derivative thereof" could read on any derivatives of lignin which includes bioactive or bio-inactive derivatives and some of derivative of lignin may be harmful or toxic to a mammal being treated. Therefore, the claims are indefinite since one of ordinary skill in the art could not ascertain and interpret the metes and bounds as to "derivatives thereof" and "a derivative thereof" as the patent protection desired in the instant invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35, 39-42 and 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Pillai et al. for the same reasons of record in the previous Office Action July 1, 2003.

Pillai et al. discloses a composition or compositions comprising ligin-derived macromolecules (LDM) containing lignosulfonates and/or lignosulfonic acids, isolated from a lignin, and a sperm in an aqueous solution (a pharmaceutical excipient) in varying concentrations, wherein LDM may inhibit the sperm acrosome reaction (see

page 140, "Introduction" lines 1-4 and the last seven lines of "Introduction", the particular tested samples at page 142, entitled "2.5 Effect of LDM and electroeluted LDM bands on sperm acrosome reaction" the 1st paragraph, and the last three lines at page 144, and the 2nd paragraph of page 145). It is noted that lignin is known from a woody plant (see the definition of lignin - its ordinary and customary meaning provided by the American Heritage Dictionary, Second College Edition, 1982, page 730, PTO-892; see also US 5,698,524 abstract, PTO-1449 submitted November 25, 2002).

Thus, the disclosure of Pillai et al. anticipates claims 35, 39-42 and 49-50.

Applicant's remarks filed January 20, 2004 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicant's assertion that "Pillai does not teach compositions comprising a pharmaceutically acceptable excipient as recited in each of the instant independent claims, from which the other claims in question depend". Contrary to Applicant's assertion, the aqueous solution of Pillai et al. comprising ligin-derived macromolecules (LDM) containing lignosulfonates and/or lignosulfonic acids, isolated from a lignin, and a sperm clearly anticipates the instant compositions since water is a well known pharmaceutically acceptable excipient. Applicant also argues that seawater buffered with glutaraldehyde or paraformaldehyde, are not pharmaceutically acceptable excipients. Note that the transitional phrases "comprising" is employed in the instant claimed composition. Applicant is requested to note that the transitional term

"comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See MPEP 2111.03.

In response to Applicant's argument that "the Pillai constituents are for an in vitro assay, not for pharmaceutical use", the instant claims are not limited to in vivo or in vitro. Therefore, it is irrelevant whether the reference includes those features or not. Moreover, note that "LSA Prevents In Vitro Fertilization" in the specification (see Example 2 at page 25 of the specification). Further, a recitation of the intended use of a composition is not considered a limitation of the composition itself. See for example, *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37, 43-44, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pillai et al. and Anderson et al. (6,063,773) for the same reasons of record in the previous Office Action July 1, 2003.

The same disclosure of Pillai et al. has been discussed in the previous Office action and above.

Anderson et al. (6,063,773) discloses that the known spermicide, nonoxynol-9, is known to be useful in a pharmaceutical composition for contraception or inhibiting fertilization. See abstract, col.1 lines 23-32 and col.3 lines 13-16 in particular.

Pillai et al. and Anderson et al. do not expressly disclose the employment of a lignosulfonate or a lignosulfonic acid in combination with a spermicide such as nonoxynol-9 in a pharmaceutical composition.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a lignosulfonate or a lignosulfonic acid in combination with a spermicide such as nonoxynol-9 in a pharmaceutical composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a lignosulfonate or a lignosulfonic acid in combination with a spermicide such as nonoxynol-9 in a pharmaceutical composition since both a lignosulfonate or a lignosulfonic acid, and the known spermicide, nonoxynol-9, are known to be useful in a composition for contraception or inhibiting fertilization based on the cited prior art. Therefore, one of ordinary skill in the art would have reasonably expected that combining a lignosulfonate or a lignosulfonic acid and nonoxynol-9, both known useful for the same purpose, would improve the therapeutic effects for contraception or inhibiting fertilization, and/or would produce additive therapeutic effects in treating the same. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) regarding combination inventions. It is considered prima facie obvious to combine two active composition components into a single composition to form a third composition useful for

the very same purpose; idea of combining them flows logically from their having been individually taught in prior art. .

Response to Argument

Applicant's arguments filed January 20, 2004 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant's assertion that the there is no motivation to combine the references has been considered but is not found persuasive. It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form a third composition that is to be used for the very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06. In the instant case, as discussed in the set forth 103(a) rejection, both a lignosulfonate or a lignosulfonic acid, and the known spermicide, nonoxynol-9, are known to be useful in a composition for contraception or inhibiting fertilization based on the cited prior art. Therefore, one of ordinary skill in the art would have reasonably expected that combining a lignosulfonate or a lignosulfonic acid and nonoxynol-9, both known useful for the same purpose, would improve the therapeutic effects for contraception or inhibiting fertilization, and/or would produce additive therapeutic effects in treating the same, absent evidence to the contrary.

Applicant's data shown in the Examples 1-3 of the specification at pages 21-30 herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art, since Examples 1-3 provide no clear and convincing evidence of nonobviousness or unexpected results of the claimed combination of a lignosulfonate or a lignosulfonic acid with a spermicide such as nonoxynol-9 over the cited prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

SHAOJIA ANNA JIANG
PATENT EXAMINER

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
April 12, 2004